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EXAMINER	
HEVEY, JOHN A	

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1793	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,338	GROVER ET AL.	
	Examiner	Art Unit	
	JOHN A. HEVEY	1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/2007, 11/09/2007, 12/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Claims 1-23 are amended; claims 24-40 are newly added claims. Claims 1-40 are pending and presented for examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 5-8, 29-31, and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerch et al. (US6018095).

Claim 1 is drawn to a bone cement comprising a calcium component and a liquid component comprising pyrophosphate ions and water.

In regards to claims 1, 5-8, and 29 Lerch et al. ("Lerch") teaches an implantable composite material composition comprising beta-tricalcium phosphate (beta-TCP) a source of calcium and anhydrous sodium pyrophosphate added to an aqueous solution of orthophosphoric acid and

sulfuric acid (see col. 4 line 63 to col. 5, line 5) to form a uniform mixture of hardenable liquid solution.

Although Lerch teaches a powdered anhydrous sodium pyrophosphate added to the aqueous solution, this is considered to anticipate the instant claim. The sodium pyrophosphate when added to solution will inherently form pyrophosphate ions. Therefore a composition listing dry components and liquid components which are to be mixed, is equivalent to a composition listing the "dry" ingredients in solution. As the claim is drawn to a product, the particular process to form said product is not given patentable weight, unless it materially affects the resulting structure. The reference teaches all the elements required by claims 1, 5-8, and 29 and therefore anticipates said claims.

In regards to claim 2 and 31, Lerch teaches a specific embodiment in which 2.954 g of beta-TCP and .046 g of anhydrous sodium pyrophosphate is added to 2.3 mL of an aqueous solution of orthophosphoric acid 4 M and sulfuric acid 0.1 M. This equates to approximately 1.28 g/mL, anticipating claim 2.

In regards to claim 38, the claim defines the product by how the product was made. Thus, claim 38 is a product-by-process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113.

Lerch teaches the required cement composition (see above) and teaches mixing and drying of said composition to form a solid (see example 1).

In regards to claims 30 and 39, Lerch teaches a specific example composition with a setting time of 5 minutes, anticipating the instant ranges (see example 1).

In regards to claim 40, Lerch teaches the required cement composition (see above) and teaches a method of making a solid cement by mixing said composition and allowing to dry (see example 1).

3. Claims 1-7 and 20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bohner et al. (US6733582).

Claim 1 is drawn to a bone cement comprising a calcium component and a liquid component comprising pyrophosphate ions and water.

In regards to claims 1 and 4-7, Bohner et al. (Bohner) teaches a cement composition comprising a first component comprising a basic calcium phosphate, a second component comprising an acidic phosphate, a third component comprising water, and a fourth component comprising a magnesium salt (see claim 1).

Bohner teaches said first component to include beta-TCP, alpha-TCP, tetracalcium phosphate (TTCP), and hydroxyapatite (see claims 2-6), second component to include monocalcium phosphate and sodium pyrophosphate (see claim 9 and example 4), third component to include water and may further include phosphoric acid (orthophosphoric acid, OPA) and sulfuric acid (see col. 4, lines 7-11), and fourth component to include magnesium pyrophosphate and

other magnesium salts (see claim 13). The reference also teaching the addition of a setting time additive including sodium pyrophosphate, potassium pyrophosphate, and others which may be pre-dissolved or added as a solid (see col. 3, lines 51-67).

The reference teaches specific embodiments comprising beta-TCP, MCPM, sodium pyrophosphate, calcium pyrophosphate and other components (see example 4) and further teaches an embodiment wherein the primary source of calcium, beta-TCP has a mean particle size of 1.1 micrometer reading on claim 4 (see example 2, col. 6).

Bohner teaches a composition comprising a source of calcium, a source of pyrophosphate ions and water. The pyrophosphate salts when added to solution will inherently form pyrophosphate ions. Therefore a composition listing dry components and liquid components which are to be mixed, is equivalent to a composition listing the dry ingredients in solution. As the claim is drawn to a product, the particular process to form said product is not given patentable weight, unless it materially affects the resulting structure. The reference teaches all the elements required by claims 1 and 4-7 and therefore anticipates said claims.

In the alternative, it would have been obvious to select a composition including a pre-dissolved pyrophosphate salt as described above as a source of pyrophosphate ions in order to regulate the setting time of the cement.

In regards to claims 2 and 3, Bohner teaches a specific example comprising 5.33 g HA, 2.66 g MCPM, 4 g TCP (calcium components), 20 mg sodium pyrophosphate, 100 mg sodium sulfate, and 600 mg magnesium pyrophosphate, mixed in 6 mL of an aqueous xanthan solution (see example 4). This is equivalent to approximately 1.8 g/mL of calcium component to the liquid component including pyrophosphate ions, anticipating the instant ranges.

In the alternative, it would have been obvious to one of ordinary skill in the art to select from the portion of the overlapping ranges. Overlapping ranges have been found sufficient to form a case of prima facie obviousness.

In regards to claim 20, the claim defines the product by how the product was made. Thus, claim 38 is a product-by-process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. The claim implies the structure of a bone cement, but does not imply a compacted cement as the required range include 0 Mpa. Bohner teaches the required cement according to claim 1 (see above) and therefore anticipates the instant claim.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 8-19 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohner et al. (US6733582).

In regards to claim 8, Bohner teaches a setting time additive to include orthophosphate salts (a source of orthophosphate ions) and said third component may further include orthophosphoric acid (OPA)(see col. 4, lines 2-11). It would have been obvious to one of ordinary skill in the art to use additionally a source of orthophosphate ions or orthophosphoric acid as taught by Bohner in order to adjust the setting time of the cement.

In regards to claims 9-17, Bohner teaches a fourth component present in the amount of 0.001-60% selected from magnesium pyrophosphate and other magnesium salts, and also teaches a setting rate controller can be added pre-dissolved selected from sodium pyrophosphate, potassium pyrophosphate, and others (see col. 3, lines 47-67). It would have been obvious to one of ordinary skill in the art to select from the overlapping portion of the ranges. Overlapping ranges have been found sufficient to establish a prima facie case of obviousness.

The reference teaches a third component to include water and may further include orthophosphoric acid (see above); however, Bohner is silent as to the specific amounts of said water and orthophosphoric acid.

However, Bohner establishes that the amount of phosphoric acid is a result effective variable (see column 4, lines 7-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose the instantly claimed ranges through process optimization, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See *In re Boesch*, 205 USPQ 215. One would have been motivated to do so in order to obtain the desired setting time by optimizing the amount of phosphoric acid relative to water and thus to maximize the industrial applicability of the invention.

In regards to claims 18-19 and 24-28, Bohner teaches the addition of a setting time additive (setting retardant) to include sodium pyrophosphate, potassium pyrophosphate, sodium acetate as well as orthophosphate salts and chitosan (see col. 3, lines 51-67 and claims 16-18). Regarding claims 25 and 28 respectively, the reference teaches a wherein a setting time of the cement paste at 25 C is between 1 and 20 minutes (see claim 22) and teaches the further addition of orthophosphoric acid (see above).

Claim 29 is an independent claim drawn to a bone cement composition comprising a calcium component selected from beta-TCP, alpha-TCP, TTCP, DCPA, DCPD, HA, and CaO and a liquid component comprising pyrophosphoric

acid, orthophosphoric acid and water. Claims 29-37 are drawn to the same subject matter as rejected claims 1-3, 6, 16-19, and 24-28. Thus, it would have been obvious to one of ordinary skill in the art to select a cement composition as required by claims 29-37 as taught by Bohner (see rejections of claims 1-3, 6, 16-19, and 24-28).

In regards to claim 38, the claim defines the product by how the product was made. Thus, claim 38 is a product-by-process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113.

Bohner teaches a cement composition comprising a calcium component such as beta-TCP, alpha-TCP, and HA, as well as a liquid component comprising pyrophosphoric acid, orthophosphoric acid, and water (see above rejections). For sake of clarity, the reference also teaches that the cement may be used as a bone substitute (see col. 5, lines 30-35) and a cement can be formed by mixing said components, ejection of the mixed cement composition onto a desired setting, and drying (see examples 1-4).

In regards to claim 39, Bohner teaches a setting time of 1-20 minutes (see claim 22).

In regards to claim 40, Bohner teaches a cement composition comprising a calcium component such as beta-TCP, alpha-TCP, and HA, as well as a liquid component comprising pyrophosphoric acid, orthophosphoric acid, and water (see above rejections). The reference also teaches that the cement may be used

as a bone substitute (see col. 5, lines 30-35) and teaches a method of making a cement comprising mixing said components, ejection of the mixed cement composition onto a desired setting, and drying (see examples 1-4).

4. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohner et al. (US6733582) as applied to claim 1 above, in view of Chae et al. (US6537589).

Bohner fails to teach the addition of a polyphosphate salt as required by claim 21. Chae et al. teaches a calcium phosphate cement comprising a polyphosphate additive (see col. 9, lines 34-67). It would have been obvious to one of ordinary skill in the art to modify the teachings of Bohner to include a polyphosphate salt as taught by Chae in order to promote bone regeneration in combination with the artificial bone cement (see col. 9, lines 48-51).

In regards to claim 23, Chae teaches said polyphosphate in chain lengths of 3-200 (see claim 5). Therefore, it would have been obvious to one of ordinary skill in the art to select from the portion of the overlapping ranges.

5. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bohner et al. (US6733582) in view of Chae et al. (US6537589) as applied to claim 21, further in view of Constantz (US4880610).

Bohner in view of Chae fail to teach the use of calcium hydroxide as a source of calcium. Constantz teaches a calcium phosphate material in which

calcium hydroxide is employed to adjust the pH of the cement in relation to the amount of water and phosphoric acid (see col. 4, lines 62-68).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Bohner in view of Chae, to add calcium hydroxide as a source of calcium in order to regulate the pH of the bone cement composition.

Response to Arguments

6. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN A. HEVEY whose telephone number is (571)270-3594. The examiner can normally be reached on Monday - Friday 7:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anthony J. Green/

Primary Examiner, Art Unit 1793

jah